

	Office of Sponsor and Regulatory Oversight	Document #: 101
	Good Documentation Practices Policy	Revision #: 3
		Effective Date: 05JAN2024

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Good Documentation Practices (GDP) policy.

2. Scope


- 2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.
- 2.2. The following documents are within the scope of this policy:
 - 2.2.1. Essential documents for trials under CCR-held Investigational New Drug applications (IND), Investigational Device Exemption (IDE) studies, Non-Significant Risk Device studies (NSR), and documents that reside in the Trial Master File (TMF). Refer to ICH E6(R2) for a list of Essential Documents.
 - 2.2.2. Source documents including all trial original documents, data and records.
 - 2.2.3. OSRO (Sponsor) Quality Management System (QMS) documents.
- 2.3. Limitations
 - 2.3.1. Personnel are not bound to this policy when working on non-IND, IDE or NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.
 - 2.3.2. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

- 3.1. CCR Management is committed to providing resources to meet the requirements for implementing a GDP policy within OSRO's QMS to achieve quality objectives and supporting the program's continual improvement.
- 3.2. OSRO personnel are responsible for understanding and using Good Documentation Practices.
- 3.3. The OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff who assist OSRO Functional Groups are responsible for understanding and using Good Documentation Practices.
- 3.4. The OSRO Director is responsible for establishing and maintaining OSRO's Good Documentation Practices policy.
- 3.5. CCR Clinical groups are responsible for maintaining and providing documents that comply with OSRO's GDP Policy.

4. References

- 4.1. [ICH E6\(R2\)](#) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

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4.2. [Annex 4](#): Guideline on Data Integrity, World Health Organization Technical Report Series No. 1033, October 2021

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO Good Documentation Practices

6.1.1. OSRO’s documentation practices shall be standardized for creating, correcting, and managing data, documents and records. This will ensure that documentation of activities is kept in a consistent, transparent manner that will assure the reliability, integrity and traceability of information and data throughout all aspects of clinical research.

6.1.1.1. These practices apply to paper and electronic data and records produced within the scope of both the QMS and clinical research.

6.1.1.2. These practices do not apply to loose unofficial papers, notes and uncontrolled documents.

6.1.2. Procedures shall be established for the preparation, reviewing, approving, issuing, recording, storing and archiving documents, records and data generated by OSRO.

6.1.3. Procedures shall be established for the resolution of discrepancies, omissions or issues that render OSRO reviewed (i.e. source documents), OSRO received (i.e. essential documents) and OSRO generated documents out of compliance with this policy.

6.2. OSRO Good Documentation Practices shall follow the Food and Drug Administration’s (FDA) key attributes for good documentation known as ALCOA-C – Attributable, Legible, Contemporaneous, Original, Accurate and Complete.

6.2.1. Attributable – information is captured in the record so that it is uniquely identified as having been executed by the originator (e.g. a person or computer system).

6.2.2. Legible, traceable, and permanent – information is readable, understandable, and allows a clear picture of the order of steps or events in the record.

6.2.3. Contemporaneous – recorded at the time data are generated or observed.

6.2.4. Original (or “True Copy”) – data in the format in which it was originally generated, preserving the integrity (accuracy, completeness, content and meaning) of the record.

6.2.5. Accurate – data are correct, truthful, complete, valid and reliable.

6.2.6. Complete – adequate, accurate and complete source documents and source data are maintained.

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7. Change Summary

Revision Number	Effective Date	Description of Change
1	02Aug2019	New Document
2	03JAN2022	Biennial review Step 2.2.1 – added NSR language Step 2.3.1 – added Step 3.3 – added Step 4.1 – added hyperlink Step 4.2 – added reference and hyperlink for ALCOA Updated document language as needed
3	05JAN2024	Biennial review Step 4.2 – updated reference and hyperlink for ALCOA